shall be subject to reinspection by a Program employee at the official establishment in such manner and at such times as may be deemed necessary to assure compliance with the regulations in this subchapter.

(b) All products, whether fresh, cured, or otherwise prepared, even though previously inspected and passed, shall be reinspected by Program employees as often as they may deem necessary in order to ascertain that they are not adulterated or misbranded at the time they enter or leave official establishments and that the requirements of the regulations in this subchapter are complied with.

(c) Reinspection may be accomplished through use of statistically sound sampling plans that assure a high level of confidence. The circuit supervisor shall designate the type of plan and the program employee shall select the specific plan to be used in accordance with instructions issued by the Administrator.[1]

(d) A U.S. retained tag shall be placed by a Program employee at the time of reinspection at any official establishment on all products which are suspected on such reinspection of being adulterated or misbranded, and such products shall be held for further inspection. Such tags shall be removed only by authorized Program employees. When further inspection is made, if the product is found to be adulterated, all official inspection legends or other official marks for which the product is found to be ineligible under the regulations in this subchapter, shall be removed or defaced and the product will be subject to condemnation and disposal in accordance with part 314 of this subchapter, except that a determination regarding adulteration may be deferred if a product has become soiled or unclean by falling on the floor or in any other accidental way or if the product is affected with any other condition which the inspector deems capable of correction, in which case the product shall be cleaned (including trimming if necessary) or otherwise handled in a manner approved by the inspector to assure that it will not be adulterated or misbranded and shall then be presented for reinspection and disposal in accordance with this section. If upon final inspection, the product is found to be neither adulterated nor misbranded, the inspector shall remove the U.S. retained tag. If a product is found upon reinspection to be misbranded, it shall be held under a U.S. retained tag, or a U.S. detention tag as provided in part 329 of this subchapter, pending correction of the misbranding or issuance of an order under section 7 of the Act to withhold from use the labeling or container of the product, or the institution of a judicial seizure action under section 403 of Act or other appropriate action. The inspector shall make a complete record of each transaction under this paragraph and shall report his action to the area supervisor.

[35 FR 15586, Oct. 3, 1970; 36 FR 11903, June 23, 1971]

§ 318.3 Designation of places of receipt of products and other articles for reinspection.

Every official establishment shall designate, with the approval of the circuit supervisor, a dock or place at which products and other articles subject to reinspection under § 318.2 shall be received, and such products and articles shall be received only at such dock or place.

§ 318.4 Preparation of products to be officially supervised; responsibilities of official establishments; plant operated quality control.

(a) All processes used in curing, pickling, rendering, canning, or otherwise preparing any product in official establishments shall be supervised by Program employees unless such preparation is conducted as a custom operation exempted from inspection under

[1] Further information concerning sampling plans which have been adopted for specific products may be obtained from the Circuit Supervisors of Program circuits. These sampling plans are developed for individual products by the Washington staff and will be distributed for field use as they are developed. The type of plan applicable depends on factors such as whether the product is in containers, stage of preparation, and procedures followed by the establishment operator. The specific plan applicable depends on the kind of product involved, such as liver, oxtails, etc.

§ 303.1(a)(2) of this subchapter in any official establishment or consists of operations that are exempted from inspection under § 303.1(d) of this subchapter and are conducted in a retail store in an establishment subject to inspection only because the State or Territory in which the establishment is located is designated under paragraph 301(c) of the Act. No fixtures or appliances, such as tables, trucks, trays, tanks, vats, machines, implements, cans, or containers of any kind, shall be used unless they are of such materials and construction as will not contaminate or otherwise adulterate the product and are clean and sanitary. All steps in the preparation of edible products shall be conducted carefully and with strict cleanliness in rooms or compartments separate from those used for inedible products.

(b) It shall be the responsibility of the operator of every official establishment to comply with the Act and the regulations in this subchapter. In order to carry out this responsibility effectively, the operator of the establishment shall institute appropriate measures to assure the maintenance of the establishment and the preparation, marking, labeling, packaging and other handling of its products strictly in accordance with the sanitary and other requirements of this subchapter. The effectiveness of such measures will be subject to review by the Department.

(c) *Applying for Total Plant Quality Control.* Any owner or operator of an official establishment preparing meat food product who has a total plant quality control system or plan for controlling such product, after antemortem and post-mortem inspection, through all stages of preparation, may request the Administrator to evaluate it to determine whether or not that system is adequate to result in product being in compliance with the requirements of the Act and therefore qualify as a U.S. Department of Agriculture (USDA) Total Plant Quality Control Establishment. Such a request shall, as a minimum, include:

(1) A letter to the Administrator from the establishment owner of operator stating the company's basis and purpose for seeking an approved quality control system and willingness to adhere to the requirements of the system as approved by the Department; that all the establishment's data, analyses, and information generated by its quality control system will be maintained to enable the Department to monitor compliance and available to Department personnel; that plant quality control personnel will have authority to halt production or shipping of product in cases where the submitted quality control system requires it; and that the owner or operator (or his/her designee) will be available for consultation at any time Department personnel consider it necessary.

(2) In the case of an establishment having one or more full-time persons whose primary duties are related to the quality control system, an organizational chart showing that such people ultimately report to an establishment official whose quality control responsibilities are independent of or not predominantly production responsibilities. In the case of an establishment which does not have full-time quality control personnel, information indicating the nature of the duties and responsibilities of the person who will be responsible for the quality control system.

(3) A list identifying those parts and sections of the Federal meat inspection regulations which are applicable to the operations of the establishment applying for approval of a quality control system. This list shall also identify which part of the quality control system will serve to maintain compliance with the applicable regulations.

(4) Detailed information concerning the manner in which the system will function. Such information should include, but not necessarily be limited to, questions of raw material control, the critical check or control points, the nature and frequency of tests to be made, the nature of charts and other records that will be used, the length of time such charts and records will be maintained in the custody of the official establishment, the nature of deficiencies the quality control system is designed to identify and control, the parameters or limits which will be used, and the points at which corrective action will occur and the nature of such corrective action—ranging from

least to most severe: *Provided,* That, subsequent to approval of the total plant quality control system by the Administrator, the official establishment may produce a new product for test marketing provided labeling for the product has been approved by the Administrator, the inspector in charge has determined that the procedures for preparing the product will assure that all Federal requirements are met, and the production for test marketing does not exceed 6 months. Such new product shall not be produced at that establishment after the 6-month period unless approval of the quality control system for that product has been received from the Administrator.

(d) *Partial Quality Control Programs.* (1) Any owner or operator of an official establishment preparing meat food products who is required to have a quality control program for a product operation, or part of an operation shall make the written program and data and information generated by the program available to Program employees.

(2)(i) This quality control program shall include, as appropriate for the operation which the program concerns, detailed information on: raw material control, the critical check or control points, the nature and frequency of tests to be made, the charts and records that will be used, the length of time such charts and records will be maintained in the custody of the official establishment, the limits that will be used and the points at which corrective action will be taken to prevent recurrence of a loss of control, and the nature of the corrective action—ranging from the least to the most severe.

(ii) This quality control program shall ensure that the product, operation, or part of an operation which it concerns is in control and that applicable product or label limits are being met. Process control is to be determined by generally recognized statistical process control procedures.

(e) *Evaluation and Approval of Total Plant Quality Control.* (1) The Administrator shall evaluate the material presented in accordance with the provisions of paragraph (c) of this section. If it is determined by the Administrator, on the basis of the evaluation, that the total quality control system will result in finished products controlled in this manner being in full compliance with the requirements of the Act and regulations thereunder, the total quality control system will be approved and plans will be made for implementation under departmental supervision.

(2) In any situation where the system is found by the Administrator to be unacceptable, formal notification shall be given to the applicant of the basis for the denial. The applicant will be afforded an opportunity to modify the system in accordance with the notification. The applicant shall also be afforded an opportunity to submit a written statement in response to this notification of denial and a right to request a hearing with respect to the merits or validity of the denial. If the applicant requests a hearing and the Administrator, after review of the answer, determines the initial determination to be correct, he shall file with the Hearing Clerk of the Department the notification, answer and the request for hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with Rules of Practice which shall be adopted for this proceeding.

(3) The establishment owner or operator shall be responsible for the effective operation of the approved total plant quality control system to assure compliance with the requirements of the Act and regulations thereunder. The Secretary shall continue to provide the Federal inspection necessary to carry out his responsibilities under the Act.

(f) *Labeling Logo.* Owners and operators of official establishments having a total plant quality control system approved under the provisions of paragraph (c) of this section, may only use, as a part of any labeling, the following logo. Any labeling bearing the logo and any wording of explanation with respect to this logo shall be approved as required by parts 316 and 317 of this subchapter.

(g) *Termination of Total Plant Quality Control.* (1) The approval of a total plant quality control system may be terminated at any time by the owner or operator of the official establishment upon written notice to the Administrator.

(2) The approval of a total plant quality control system may be terminated upon the establishment's receipt of a written notice from the Administrator under the following conditions:

(i) If adulterated or misbranded meat food product is found by the Administrator to have been prepared for or distributed in commerce by the subject establishment. In such case, opportunity will be provided to the establishment owner or operator to present views to the Administrator within 30 days of the date of terminating the approval. In those instances where there is conflict of facts, a hearing, under applicable Rules of Practice, will be provided to the establishment owner or operator to resolve the conflict. The Administrator's termination of approval shall remain in effect pending the final determination of the proceeding.

(ii) If the establishment fails to comply with the quality control system or program to which it has agreed after being notified by letter from the Administrator or his designee. Prior to such termination, opportunity will be provided to the establishment owner or operator to present views to the Administrator within 30 days of the date of the letter. In those instances where there is a conflict of facts, a hearing, under applicable Rules of Practice, will be provided to the establishment owner or operator to resolve the conflict. The Administrator's termination of quality control approval shall remain in effect pending the final determination of the proceeding.

(3) If approval of the total establishment quality control system has been terminated in accordance with the provisions of this section, an application and request for approval of the same or a modified total establishment quality control system will not be evaluated by the Administrator for at least 6 months from the termination date.

(h)(1) *Operating Schedule Under Total Plant Quality Control.* An official establishment with an approved total plant quality control system may request approval for an operating schedule of up to 12 consecutive hours per shift. Permission will be granted provided that:

(i) The official establishment has satisfactorily operated under a total plant quality control system for at least 1 year.

(ii) All products prepared and packaged, or processed after the end of 8 hours of inspection shall only be a continuation of the processing monitored by the inspector and being conducted during the last hour of inspection.

(iii) All immediate containers of products prepared and packaged shall bear code marks that are unique to any period of production beyond the 8 hours of inspection. The form of such code marks will remain constant from day to day, and a facsimile of the code marks and their meaning shall be provided to the inspector.

(2) *Application.* Applications shall be submitted to the Regional Director and shall specify how the conditions in §318.4(h)(1) have been or will be met.

(3) *Monitoring by Inspectors.* In order to verify that an establishment is preparing and shipping product in accordance with the approved total plant quality control system and the Act and regulations after the 8 hours of inspection, the official establishment may be provided overtime inspection services at the discretion of the circuit supervisor and charged for such services.

(Reporting requirements were approved by the Office of Management and Budget under control number 0583–0015)

[35 FR 15586, Oct. 3, 1970, as amended at 36 FR 12003, June 24, 1971; 45 FR 54322, Aug. 15, 1980; 51 FR 32304, Sept. 11, 1986; 62 FR 45024, Aug. 25, 1997; 62 FR 54759, Oct. 22, 1997]

§ 318.5 Requirements concerning procedures.

(a)(1) Care shall be taken to assure that product is not adulterated when placed in freezers. If there is doubt as to the soundness of any frozen product, the inspector will require the defrosting and reinspection of a sufficient quantity thereof to determine its actual condition.

(2) Frozen product may be defrosted in water or pickle in a manner and with the use of facilities which are acceptable to the inspector. Before such product is defrosted, a careful examination shall be made to determine its condition. If necessary, this examination shall include defrosting of representative samples by means other than in water or pickle.

(b) Product, such as pork tenderloins, brains, sweetbreads, stew, or chop suey, shall not be packed in hermetically sealed metal or glass containers, unless subsequently heat processed or otherwise treated to preserve the product in a manner approved by the Administrator in specific cases.

(c) Care shall be taken to remove bones and parts of bones from product which is intended for chopping.

(d) Heads for use in the preparation of meat food products shall be split and the bodies of the teeth, the turbinated and ethmoid bones, ear tubes, and horn butts removed, and the heads then thoroughly cleaned.

(e) Kidneys for use in the preparation of meat food products shall first be freely sectioned and then thoroughly soaked and washed. All detached kidneys, including beef kidneys with detached kidney fat, shall be inspected before being used in or shipped from the official establishment.

(f) Cattle paunches and hog stomachs for use in the preparation of meat food products shall be thoroughly cleaned on all surfaces and parts immediately after being emptied of their contents, which shall follow promptly their removal from the carcasses.

(g) Clotted blood shall be removed from hog hearts before they are shipped from the official establishment or used in the preparation of meat food products.

(h) Beef rounds, beef bungs, beef middles, beef bladders, calf rounds, hog bungs, hog middles, and hog stomachs which are to be used as containers of any meat food product shall be presented for inspection, turned with the fat surface exposed.

(i) Portions of casings which show infection with Oesophagostomum or other nodule-producing parasite, and weasands infected with the larvae of Hypoderma lineatum, shall be rejected, except that when the infestation is slight and the nodules and larvae are removed, the casing or weasand may be passed.

[35 FR 15586, Oct. 3, 1970; 36 FR 11903, June 23, 1971]

§ 318.6 Requirements concerning ingredients and other articles used in preparation of products.

(a) All ingredients and other articles used in the preparation of any product shall be clean, sound, healthful, wholesome, and otherwise such as will not result in the product being adulterated. Official establishments shall furnish inspectors accurate information on all procedures involved in product preparation including product composition and any changes in such procedures essential for inspectional control of the product.

(b)(1) The only animal casings that may be used as containers of product are those from cattle, sheep, swine, or goats.

(2) Casings for products shall be carefully inspected by Program employees. Only those casings which have been carefully washed and thoroughly flushed with clean water immediately before stuffing and are suitable for containers, are clean, and are passed on such inspection shall be used, except that preflushed animal casings packed in salt or salt and glycerine solution or other approved medium may be used without additional flushing provided they are found to be clean and otherwise acceptable and are thoroughly rinsed before use.